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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/786,309 | 06/06/2001 | Masayoshi Mishina | 55573 | 8081 |

7590 12/12/2002

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[REDACTED] EXAMINER

PARAS JR, PETER

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1632

DATE MAILED: 12/12/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/786,309 | MISHINA ET AL. | |
| Examiner | Art Unit | | |
| Peter Paras, Jr. | 1632 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 December 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 8-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 8-22 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 06 June 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 12/31/02 has been entered. Claims 1-7 have been cancelled. New claims 8-22 have been added. Claims 8-22 are pending and are under current consideration.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Peter Paras, Jr. of Art Unit 1632.

Drawings

New corrected drawings are required in this application because of the objections cited by the Draftsman on the attached PTO-948. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The previous rejection of claims 1-7 under 35 U.S.C. 101 is withdrawn.

The following are new ground of rejection under 35 U.S.C. §112, 2nd paragraph:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is incomplete as written. The preamble of the claim is directed to a mutagenesis method of a gene of a vertebrate animal however, the claim as written lacks positive process steps that relate to the goal of the preamble. Claims 9-12 depend from claim 8.

Claim 13 is incomplete as written. The preamble of the claim is directed to a method for preparation of a mutated gene of a vertebrate animal however, the claim as written lacks positive process steps that relate to the goal of the preamble. Claims 14-17 depend from claim 13.

Claim 18 is incomplete as written. The preamble of the claim is directed to a method for analyzing the function of a gene of a vertebrate animal however, the claim as written lacks positive process steps that relate to the goal of the preamble. Claims 19-22 depend from claim 18.

Claim 18 recites the limitation "the mutant phenotype" in step e. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The previous rejection of claims 1-2 and 5-7 rejected 35 U.S.C. 102(b) as being anticipated by Glazer et al is withdrawn.

The following are new grounds of rejection under 35 § U.S.C. 102:

Claims 8-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ando et al (Neuroscience Letters, 1998:81-84; IDS reference--AA).

Ando et al teach a method for mutating DNA of zebrafish to generate mutant zebrafish that comprise a mutated gene, wherein the mutant zebrafish can be analyzed at the molecular level and the mutation is correlated to a mutant phenotype. See abstract, and page 82. The method comprises obtaining sperm from male zebrafish, incubating the sperm in a 4,5',8-trimethylpsoralen (TMP) solution, irradiating the incubated sperm with ultraviolet (UV) light to create mutant sperm, fertilizing zebrafish oocyte with the mutant sperm to create a mutant zebrafish embryo, and allowing the

mutant zebrafish embryo to develop into a zebrafish. Ando et al further teach that activation of TMP by UV irradiation induces covalent binding to pyrimidine residues of DNA double helices and cross-linking of DNA, thereby mutagenizing a region containing a pyrimidine base. See page 84.

Thus, the teachings of Ando et al meet all of the instant claim limitations.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.
Art Unit 1632

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